

2018 Current Fiscal Year Report: National Vaccine Advisory Committee

Report Run Date: 06/05/2019 12:14:30 PM

1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2018

3. Committee or Subcommittee

National Vaccine Advisory Committee

3b. GSA Committee No.

971

4. Is this New During Fiscal Year?

No

5. Current Charter

07/30/2017

6. Expected Renewal Date

07/30/2019

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

42 U.S.C. 300aa-5

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority

42 U.S.C. 300aa-5

13. Effective Date

11/14/1986

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee National Policy Issue Advisory Board

16a. Total Number of Reports

1

16b. Report

Date

Report Title

Strengthening the Effectiveness of National, State, and Local Efforts to

06/25/2018Improve HPV Vaccination Coverage in the United States: Recommendations

From the Nationa

Number of Committee Reports Listed: 1

17a. Open 4 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 4

Meetings and Dates

Purpose

The February 2018 NVAC meeting consisted of presentations on vaccine innovation, including the current status of adjuvants in vaccines, universal influenza, and an overview on the Secretary of the Department of Health and Human Services' Report to Congress on Vaccine Innovation in response to the 21st Century Cures Act; a report out on the Presidential Advisory Council on Combatting Antibiotic-Resistant Bacteria Report, "Incentivizing the Development of Vaccines, Therapeutics, and Diagnostics to Combat Antibiotic Resistant Bacteria"; disparities in adult immunization; and an update on strategies to support improving coverage for human papillomavirus vaccine. During the meeting, the ASH charge the NVAC to establish a working group to produce a brief report by June 2018 on recommendations to "strengthen the effectiveness of national, state, and local efforts to improve HPV vaccination coverage rates." Specifically, the NVAC working group was asked to focus its efforts on the following four focus areas: 1) identifying additional national partners, 2) coalition-building guidance for states, 3) engagement with integrated health care delivery networks, and 4) addressing provider needs in rural areas.

Start

End

02/07/2018 - 02/08/2018

The May 3, 2018 public meeting was dedicated to the deliberation of the draft recommendations written by the NVAC HPV Vaccination Implementation work group, which was charged by the ASH at the February 2018 meeting to provide recommendations on how to strengthen the effectiveness of national, state, and local efforts to improve vaccination coverage rates. The work group is scheduled to present its findings and draft recommendations to the Committee at the June 2018 public meeting. The presentation will be followed by Committee deliberation and a vote. 05/03/2018 - 05/03/2018

The June 2018 public meeting was held virtually and included a presentation from the HPV Implementation Working Group on its findings and draft recommendations for strengthening the effectiveness of national, state, and local efforts to improve HPV vaccination coverage rates. The presentation was followed by a vote which resulted in unanimous adoption by the Committee for recommendation to the ASH. The meeting also included a presentation on the recent HHS report, "Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century," which was submitted to Congress in accordance with provisions in the 21st Century Cures Act. This presentation garnered much discussion from the Committee mainly focused on public-private partnership models for getting new vaccines to market. The meeting's final presentation was from CDC/NCIRD and provided a review of influenza communication from the 2017-2018 influenza season. The meeting also included periods for public comment. This public meeting of the National Vaccine Advisory Committee (NVAC), held September 12-13, 2018, focused on vaccine innovation. Session speakers covered a broad range of topics, including: immunization system unmet needs projects, public-private partnership models related to vaccine development, cytomegalovirus (CMV) vaccines in the pipeline, and advances in vaccination technologies. In addition, the committee head about lessons from the field around the new shingles vaccine (Shingrix), collaborative opportunities in HPV cancer prevention, and work on valuing vaccines. The two-day meeting was open to the public and was available through live webcast. 06/25/2018 - 06/25/2018 09/12/2018 - 09/13/2018

Number of Committee Meetings Listed: 4

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$25,017.03	\$26,000.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$270,566.00	\$275,000.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$39,060.83	\$40,000.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$5,500.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$80,170.34	\$85,000.00
18d. Total	\$414,814.20	\$431,500.00
19. Federal Staff Support Years (FTE)	3.80	3.30

20a. How does the Committee accomplish its purpose?

The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (P.L. 99-660) (Section 2105) (42 U.S. Code 300aa-5.). The NVAC serves an advisory role, providing peer review, consultation, advice, and recommendations to the Assistant Secretary for Health in his/her capacity as the Director of the National Vaccine Program, on matters related to the Program's responsibilities. Specifically, the committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; recommends research priorities and other measures to enhance the safety

and efficacy of vaccines; and discusses evidence-based strategies for preventing vaccine preventable diseases across all age groups through the use of vaccines. The committee also advises the Assistant Secretary for Health in the implementation of the National Vaccine Plan. The committee meets three times per year in a two-day, public, in-person meeting that is also available as a webcast to those unable to attend in person. Committee draft reports are submitted to the Federal Register for public comment, and public comment is addressed and adjudicated at the working group level, as well as publicly discussed during committee meetings. In addition, public comment periods are designated on the agenda for both days of each meeting. Following conclusion of the meeting, meeting materials and committee proceedings are made available on the Committee website at <http://www.hhs.gov/nvpo/nvac/meetings/>.

20b. How does the Committee balance its membership?

The committee consists of 17 voting members. The membership is composed of 15 public members, including the chair, and 2 members who are designated to serve as official representatives of the vaccine manufacturing industry. The public members, who are selected from individuals engaged in various aspects of the vaccine enterprise, include (but are not limited to) physicians, members of parent organizations concerned with immunization and representatives of state and local health departments or public health organizations.

20c. How frequent and relevant are the Committee Meetings?

The committee meets at a minimum three times a year. The committee deliberates and works to close gaps in immunization coverage areas that will have a substantial impact on public health policy and the prevention of infectious diseases and their complications through vaccination, by recommending actions to be taken -- by federal agencies and non-federal stakeholders -- that are involved in vaccine and immunization-related activities. Specifically, the committee offers advice and guidance on how to address existing barriers in the immunization delivery system, including strengthening immunization infrastructure, supporting providers and other partners who provide immunization services, increasing demand for immunization, and fostering vaccine development and innovation and new immunization technologies.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

NVAC's mission, laid out in its charter, is very broad. NVAC is charged with advising the on the entire range of vaccine and immunization policy which requires a depth of specialized expertise as disease burden, public trust, vaccine access, and other issues affect the immunization system.

20e. Why is it necessary to close and/or partially closed committee meetings?

NVAC committee meetings are open to the public.

21. Remarks

Ex-officio member, Tonya Rans was inadvertently left off the FY-17 ACR.

Designated Federal Officer

Ann L. Aikin Communications Officer

Committee Members	Start	End	Occupation	Member Designation
Bennett, Nancy	10/01/2015	06/30/2018	Professor of Medicine and Public Health Sciences; Director, Center for Community Health; Co-director, Clinical and Translational Science Institute, University of Rochester School of Medicine and Dentistry	Representative Member
Black, Steve	02/07/2017	02/07/2020	Professor of Pediatrics, Center for Global Child Health and Division of Infectious Diseases, University of Cincinnati Children's Hospital	Special Government Employee (SGE) Member
Blumenstock, James	10/01/2015	09/30/2019	Chief Program Officer for Health Security	Representative Member
Borrazzo, John	10/01/2016	08/16/2018	Chief, Maternal and Child Health Division, Bureau for Global Health, U.S. Agency for International Development	Ex Officio Member
Bright, Rick	10/01/2016	09/30/2019	Director, Biomedical Advanced Research and Development Authority	Ex Officio Member
Butler, Jay	02/07/2017	02/07/2020	Chief Medical Officer, Alaska Department of Health and Social Services; Director, Division of Public Health	Special Government Employee (SGE) Member
Butler, Melody	02/07/2017	02/07/2021	Pediatric Registered Nurse, Good Samaritan Hospital Medical Center	Special Government Employee (SGE) Member
Charos, Gina	11/13/2017	09/30/2019	Director, Immunization Programs and Pandemic Preparedness Division	Representative Member
Cooke, M. Timothy	09/09/2015	09/09/2019	President and Chief Executive Officer, Novadigm Therapeutics, Inc.	Representative Member
Coyle, Rebecca	10/01/2015	09/30/2019	Executive Director, American Immunization Registry Association	Representative Member
Dunn, John	02/08/2017	02/08/2020	Medical Director for Preventive Care, Kaiser Permanente Washington; Adjunct Investigator, Kaiser Permanente Washington Health Research Institute; Clinical Instructor, University of Washington School of Medicine	Special Government Employee (SGE) Member
Edwards, Kathryn	10/01/2015	09/30/2019	Sarah H. Sell and Cornelius Vanderbilt Chair in Pediatrics, Vanderbilt Vaccine Research Program, Vanderbilt University	Representative Member
Ehresmann, Kristen	10/01/2013	09/30/2019	Division Director, Infectious Disease Epidemiology, Prevention and Control, Minnesota Department of Health	Representative Member
Fleming, David	09/09/2015	09/09/2019	Vice President, Public Health Impact, PATH	Special Government Employee (SGE) Member
Friedland, Leonard	02/08/2017	02/08/2020	Vice President, Scientific Affairs and Public Health, GSK Vaccines	Representative Member

Ginsberg, Ann	09/09/2015	09/09/2019	Chief Medical Officer, AERAS	Special Government Employee (SGE) Member
Gruber, Marion	10/01/2011	09/30/2019	Director, Office of vaccines Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration	Ex Officio Member
Hopkins, Robert	02/07/2017	02/07/2021	Professor of Internal Medicine and Pediatrics; Director, Division of General Internal Medicine; Program Director, Med-Peds Residency, UAMS College of Medicine	Special Government Employee (SGE) Member
Jackson, Mary	02/08/2017	02/08/2021	Director, Division of Infectious Diseases, Children's Mercy, Kansas City; Professor of Pediatrics, University of Missouri-Kansas City School of Medicine	Special Government Employee (SGE) Member
Kelman, Jeffrey	10/01/2011	09/30/2019	Chief Medical Officer, Center for Beneficiary Choices, Centers for Medicare and Medicaid Services	Ex Officio Member
Knighton, Troy	10/01/2015	09/30/2019	National Seasonal Flu & IDPIO Program Manager, VHA National Center for Health Promotion and Disease Prevention, Department of Veterans Affairs	Ex Officio Member
Kropp, Rhonda	10/01/2015	11/13/2017	Director General, Centre for Immunization and Respiratory Infectious Disease, Public Health Agency of Canada	Representative Member
Malloy, Donna	10/01/2013	09/30/2019	Center for Veterinary Biologics, Animal and Plan Health Inspection Service/Veterinary Services, U.S. Department of Agriculture	Ex Officio Member
Martinez, Melissa	02/08/2017	02/08/2021	Medical Director, Locum Tenens and Speciality Extension Services, UNM Medical Group; Professor, Department of Internal Medicine, University of New Mexico	Special Government Employee (SGE) Member
McCollum, Jeffrey	10/01/2016	09/30/2019	Director (Acting), Division of Epidemiology and Disease Prevention, Office of Public Health Support, Indian Health Services	Ex Officio Member
Meissner, H. Cody	02/08/2017	02/08/2020	Professor of Pediatrics, Tufts University School of Medicine; Director, Pediatrics Infectious Disease, Tufts Medical Center	Special Government Employee (SGE) Member
Messonnier, Nancy	10/01/2015	09/30/2019	Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention	Ex Officio Member
Mills, Justin	10/01/2016	09/30/2019	Medical Officer, U.S. Preventive Services Task Force Program, Agency for Healthcare Research and Quality, Center for Evidence and Practice Improvement	Ex Officio Member
Mulach, Barbara	10/01/2011	09/30/2019	Director, Office of Scientific Coordination and Program Operations, Division Small Business Coordinator, Division of Microbiology and Infectious Diseases, National Institutes of Health	Ex Officio Member
Nair, Narayan	10/01/2015	09/30/2019	Acting Division Director/Chief Medical Officer, Division of Injury Compensation Programs	Ex Officio Member
Nordin, James	10/01/2016	09/30/2019	Pediatrician, HealthPartners St. Paul Medical/Dental Clinic; Clinical Research Investigator, HealthPartners Institute for Education and research; Clinical Associate Professor, Department of Pediatrics, University of Minnesota Medical School	Representative Member
Omer, Saad	09/09/2014	09/09/2018	Associate Professor Global Health, Epidemiology, and Pediatrics, Emory University Schools of Public Health & Medicine	Special Government Employee (SGE) Member
Pickering, Larry	02/08/2017	02/08/2020	Adjunct Professor of Pediatrics, Emory University School of Medicine	Special Government Employee (SGE) Member
Rans, Tonya	02/06/2017	02/05/2021	Chief, Immunization Healthcare Branch	Ex Officio Member

Smith, Nathaniel	06/10/2014	07/10/2018	Director and State Health Officer, Arkansas Department of Health	Special Government Employee (SGE) Member
Steinberg, Judith	10/01/2016	09/30/2019	Chief Medical Officer, Bureau of Primary Health Care, Health Resources and Services Administration	Ex Officio Member
Stewart, Alexandra	10/01/2016	09/30/2019	Associate Professor, George Washington University, School of Public Health and Human Services	Representative Member
Swamy, Geeta	02/08/2017	02/08/2021	Associate Dean, Regulatory Oversight & Research Initiatives; Director, Obstetrics Clinical Research; Associate Professor, Duke University Department of ObGyn, Division of Maternal-Fetal Medicine	Special Government Employee (SGE) Member
Tate, Tiffany	10/01/2013	09/30/2019	Executive Director, Maryland Partnership for Prevention	Representative Member
Thompson, Kimberly	03/02/2015	03/02/2019	Professor of Preventive Medicine and Global Health, President of Kid Risk Inc.	Special Government Employee (SGE) Member

Number of Committee Members Listed: 40

Narrative Description

The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (P.L. 99-660) (Section 2105) (42 U.S. Code 300aa-5). The NVAC serves an advisory role, providing peer review, consultation, advice, and recommendations to the Assistant Secretary for Health in his/her capacity as the Director of the National Vaccine Program, on matters related to the Program's responsibilities. Specifically, the Committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; recommends research priorities and other measures to enhance the safety and efficacy of vaccines. The Committee also advises the Assistant Secretary for Health in the implementation of the National Vaccine Plan.

What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input checked="" type="checkbox"/>
Increased customer satisfaction	<input type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Outcome Comments

- Annually reviews progress on immunization-related goals of Healthy People 2020.- Annually reviews progress on the 2010 National Vaccine Plan - Providing subject matter expertise in conducting a mid-course review of the National Vaccine Plan- Has highlighted vaccine confidence and vaccine acceptance among healthcare providers and consumers as an important priority for the Department by calling for a better understanding of methodologies to track and measure these issues.- Annually reviews progress on efforts to improve the uptake of HPV vaccination among adolescents

What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

Cost Savings Comments

Not Applicable

What is the approximate Number of recommendations produced by this committee for the life of the committee?

303

Number of Recommendations Comments

Since FY2007, the committee has approved a total of 303 individual recommendations contained within 26 sets of recommendations. These recommendations are developed through extensive subject-matter input from the NVAC working groups, as well as extensive deliberations by the full Committee. The focus of these recommendations have included: vaccine safety; pandemic H1N1 vaccine; vaccine financing of childhood and adolescent vaccinations; establishing a platform for adult immunizations; strengthening immunization information systems; supporting immunization infrastructure; improving influenza vaccination uptake in healthcare personnel; reviewing HHS efforts to support global immunization activities; overcoming patient and provider barriers to uptake of

recommended vaccines in pregnant women; promoting research and development of vaccines for use in pregnant women; improving uptake of HPV vaccination in adolescents; strategies to measure, evaluate, and promote vaccine confidence and acceptance in the U.S; and the role of vaccines in national strategies to combat antibiotic resistant bacteria. In 2018, the NVAC approved 16 individual recommendations.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

30%

% of Recommendations Fully Implemented Comments

Most of the recommendations involve actions by other HHS divisions. Therefore, NVPO can only monitor their status. However, as a routine order of business, the committee is regularly updated on the status of implementation of recommendations. NVAC will continue to take special interest in monitoring progress of the National Vaccine Plan's Implementation Plan.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

60%

% of Recommendations Partially Implemented Comments

Some recommendations have not been fully implemented due to resource limitations or remain as works in progress. Additionally, because many of the recommendations are complex, only portions have been implemented. Actions are ongoing to continue to explore further implementation.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

The Assistant Secretary for Health (ASH) functions as the Director, National Vaccine Program. In this capacity, the ASH provides guidance and direction to the Director of the National Vaccine Program Office (NVPO) for NVAC activities. The NVPO provides staffing support to the Committee and has been tasked with tracking the progress of approved recommendations. The status of Departmental efforts to implement NVAC recommendations is reported back to the Committee during their scheduled meetings.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

- | | |
|-----------------------------------|-------------------------------------|
| Reorganized Priorities | <input checked="" type="checkbox"/> |
| Reallocated resources | <input type="checkbox"/> |
| Issued new regulation | <input type="checkbox"/> |
| Proposed legislation | <input type="checkbox"/> |
| Approved grants or other payments | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Action Comments

NA

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

- | | |
|---------------------------|-------------------------------------|
| Contact DFO | <input checked="" type="checkbox"/> |
| Online Agency Web Site | <input checked="" type="checkbox"/> |
| Online Committee Web Site | <input checked="" type="checkbox"/> |
| Online GSA FACA Web Site | <input checked="" type="checkbox"/> |
| Publications | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

N/A